REMARKS

Claims 1, 3-6, 8-16, and 19-25 are pending in the subject application. Of these, claims 19-23 have been withdrawn pursuant to a restriction requirement. Hereinabove, no claims have been canceled; claims 1, 3-5, and 12, have been amended; and no new claims have been added. Therefore, claims 1, 3-6, 8-16, and 24-25, as amended, are now pending and under consideration. In view of the foregoing amendments and the following remarks, applicants respectfully request reconsideration of the objections and rejections set forth in the outstanding office action, and applicants further request that withdrawn claims 19-23 be rejoined and examined in the present application.

Applicants acknowledge the outstanding office action's indication that claims 10 and 11 are allowed.

Applicants acknowledge the outstanding office action's withdrawal of the prior rejection of claims 1-6, 8-9, 12, 14-15, and 24-25 under 35 U.S.C. § 102(b) for anticipation by International Patent Application Publication No. WO 00/14536 of Tan et al.

The rejection of claims 1, 3-6, 8-9, 12-16, and 24-25 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is respectfully traversed.

Briefly, the office action asserts that the rejected claims fail to comply with the written description requirement because the specification fails to describe the invention in sufficient detail so that one skilled in the art can clearly

conclude that the inventor invented the claimed invention. In support of this conclusion, the office action demonstrates that the claims encompass a genus that is much broader than the three specific polypeptides disclosed in the specification.

While applicants do not dispute that the claimed genus is broad and encompasses many species in addition to the three specific polypeptides disclosed in the specification, applicants submit that the specification, nevertheless, clearly demonstrates that the inventors had possession of the claimed invention.

As set out on, for example, pages 2 and 3 of the application, the inventors have found a way of allowing the activity of many protein kinases to be screened using a common format. The inventors have surprisingly found that peptides that share a common epitope are phosphorylated efficiently by many different protein kinases, which fall into several different kinase subfamilies. This was unexpected, because the prior art describes specific peptides as substrates for specific kinases, and a common epitope would not have been expected to have an appropriate conformation for phosphorylation by a range of protein kinases.

Further, not only can this common epitope be phosphorylated efficiently, but it is also the target for an effective phospho-specific antibody. Both the ability to be phosphorylated efficiently by many different protein kinases and the ability to be bound by an effective phospho-specific antibody contribute to the utility of the claimed polypeptides and kits. As set out on page 2, lines 10-22, of the

application, there are no antibodies in existence that recognize phosphoserine or phosphothreonine (independent of the surrounding amino acid context) that are sufficiently good to be usable in assays of protein kinase activity: it has previously been necessary to develop separate phosphor-specific antibodies for each serine/threonine phosphorylated substrate. The present invention overcomes this by provision of a phosphorylatable portion specified in claim 1 (SEQ ID NO:6) which is both an efficient substrate for many different protein kinases and a target for an effective phosphorylation-state sensitive antibody. Likewise, claim 12 also specifies SEQ ID NO:6.

The peptides recited in claims 1 and 12 also include a "specificity conferring portion". The specificity conferring portion comprises an amino acid sequence corresponding to a consensus sequence for a protein kinase. Consensus sequences for protein kinases are well know to those skilled in the art, and the specification and claims (e.g., claim 15) describes four such consensus sequences (SEQ ID NO:2, SEQ ID NO:5, SEQ ID NO:8, SEQ ID NO:9). Such consensus sequences are adequately described. They are well known to those skilled in the art as being the sequences necessary for phosphorylation by the specified protein kinases. Demonstrating this, there are references cited on page 3 of the specification that discuss three of these consensus sequences. The fourth sequence, Xaa-pSer-Xaa-Xaa-Ser, is also well known in the art and is discussed in, for example, Flotow et al., "Phosphate Groups as Substrate Determinants for Casein

Kinase 1 Action," J. Biol. Chem. 265(24):14264-14269 (1990) (of record).

In summary, there is no need for any narrower definition of the substrate sequences: one skilled in the art would have no difficulty whatsoever in understanding that applicants had possession of the invention, as the skilled artisan would fully understand that sequences defined in this way would have the desired properties.

For all the above reasons, it is submitted that there is ample written description of the claimed invention and that the rejection of claims 1, 3-6, 8-9, 12-16, and 24-25 under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

The objection to claims 1 and 12 as being informal because of spelling errors is respectfully traversed. Hereinabove, applicants have amended claims 1 and 12 to correct "resides" to "residues". In view of this, it is submitted that the objection should be reconsidered and withdrawn.

The objection to claims 1 and 12 as being informal because they contain phrases that include the word "capable" is respectfully traversed.

With regard to claim 1, the PTO asserts that the phrase "capable of being bound" is indefinite because it is unclear (i) if the substrate polypeptide is bound by a specific binding partner or (ii) if the substrate polypeptide is not bound by a specific binding partner. It is submitted that, in view of the context in which the phrase is used in claim 1 and in view of the teachings of the specification, the

meaning of "capable of being bound" would be clear to one skilled in the art. For example, since claim 8 depends from claim 1 and further limits claim 1 to those kits which further include a specific binding partner, claim 1 clearly encompasses kits which do not include specific binding partners. Therefore, the phrase "capable of being bound" clearly includes those situations in which the substrate polypeptide is not bound by a specific binding partner.

With regard to claim 12, the PTO asserts that the phrase "protein kinase is capable of phosphorylating the polypeptide at the serine residue" is indefinite because it is unclear (i) if the protein kinase has phosphorylated the polypeptide at the serine residue or (ii) if the protein kinase has not phosphorylated the polypeptide at the serine residue. It is submitted that, in view of the context in which the phrase is used in claim 12 and in view of the teachings of the specification, the meaning of "protein kinase is capable of phosphorylating the polypeptide at the serine residue" would be clear to one skilled in the art. For example, the polypeptide of claim 12 is disclosed as being useful for assaying the activity of a protein kinase by exposing the protein kinase to the polypeptide and determining the extent to which the polypeptide is phosphorylated (e.g., claim 20). Since, in this scenario, the polypeptide of claim 12 is not phosphorylated prior to its exposure to the protein kinase, the phrase "protein kinase is capable of phosphorylating the polypeptide at the serine residue" clearly includes those situations in which the protein kinase has not phosphorylated the polypeptide at the serine residue.

For all of the above reasons, it is submitted that the objection to claims 1 and 12 as being informal because they contain phrases that include the word "capable" should be reconsidered and withdrawn.

The rejection of claims 3-5 under 35 U.S.C. § 112, second paragraph, as being indefinite for lacking sufficient antecedent basis for the phrase "said polypeptide" is respectfully traversed. Applicants submit that "said polypeptide", as used in claims 3-5, clearly refers to the "protein kinase substrate polypeptides" recited in claim 1. However, to expedite prosecution, applicants have amended claims 3-5 to specifically refer to "said protein kinase substrate polypeptide" instead of "said polypeptide". Applicants submit that the amendments to claims 3-5 do not, in any way, narrow the scope of these claims. For all of the above reasons, it is submitted that the rejection of claims 3-5 under 35 U.S.C. § 112, second paragraph, should be reconsidered and withdrawn.

The rejection of claims 1, 3-6, 8-9, and 24-25 under 35 U.S.C. § 112, second paragraph, as being indefinite is respectfully traversed. The PTO asserts that the phrase "being bound in a phosphorylation state-sensitive manner" is unclear because the specification discloses that "by 'binding in a phosphorylation state-sensitive manner' is <u>included</u> the meaning that the specific binding partner is capable of binding to the substrate polypeptide when phosphorylated on the phosphorylatable portion, but is not capable of binding to the substrate polypeptide when it is not phosphorylated on the phosphorylatable portion" (emphasis in quotation used in office action). This passage is said to imply that there are other meanings for the term, which, in turn, renders the

phrase confusing. Applicants submit that the above-quoted passage is meant to illustrate, not define, the subject phrase. Additional illustration of the subject phrase is set forth in the specification immediately following the above-quoted passage (i.e., at page 9, lines 20-28) and in the Examples. In view of these portions of the specification and in view of the specification taken as a whole, one skilled in the art would understand the meaning of the allegedly indefinite phrase as simply referring to binding that is sensitive to the phosphorylation state of the substrate polypeptide. For all of the above reasons, it is submitted that the rejection of claims 1, 3-6, 8-9, and 24-25 under 35 U.S.C. § 112, second paragraph, should be reconsidered and withdrawn.

Withdrawn claims 19-23 are directed to methods which employ the kits and polypeptides of claims 1 and 12. Since claims 1 and 12 are patentable for all of the reasons set forth above, applicants submit that withdrawn claims 19-23 should now be rejoined and examined in the present application.

In view of the foregoing, it is submitted that this case is in condition for allowance, and such allowance is earnestly solicited.

Dated: February 18, 2009

Peter Rogalskyj
Reg. No. 38,601

The Law Office of Peter Rogalskyj
P.O. Box 44
Livonia, New York 14487-0044
Tel: 585-346-1004
Fax: 585-346-1001

Certificate of Mailing - 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

2-18-09
Date

Peter Rogalskyj